REMARKS

Claims 1, 3, 6, 8 and 10 are amended herein. Claims 2 and 9 are canceled herein.

Support for the amendment to claims 1, 6 and 8 is found, for example, at page 10, lines 19-21 and page 12, lines 12-13 and 16-18 of the specification as originally filed. Claims 3 and 10 are amended to change their dependency in view of the cancellation of claims 2 and 9.

Claim 16 is newly added claim which covers a coated capsule with first and second coating. Support for the newly added claim 16 can be found out throughout the originally filed specification, for example, page 22 lines 28-34, and Examples 9, 10 and 11 at pages 34-36.

No new matter is presented.

Upon entry of the Amendment, claims 1, 3-8, 10-12, 15 and 16 will be all of the claims pending. Of these, claim 15 is withdrawn from consideration as being drawn to a non-elected invention.

I. Response to Claim Objection

Claims 1, 6 and 8 are objected to because of the word "milleu".

Claims 1, 6 and 8 are amended herein to correct the inadvertent typographical error noted by the Examiner.

Withdrawal of the claim objection is respectfully requested.

II. Response to Claim Rejections under 35 U.S.C. §112

Claim 6 is rejected under 35 U.S.C. §112, 2nd paragraph, as allegedly being indefinite with respect to the limitation "a second coating formed by applying a coating composition comprising a film-forming polymer and one or more expandable components on the first

coating." The Examiner states that there is insufficient antecedent basis for this limitation in the claim because part (a) does not have a "first coating'.

Claim 6 is amended herein to recite a first coating as supported by the specification, for example, at page 12, lines 16-18, thereby clarifying the claimed invention and obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection.

III. Response to Claim Rejections under 35 U.S.C. §102

A. Barry et al

Claims 1-12 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Barry et al PCT/GB88/00779.

Applicants traverse the rejection.

Present claim 1 recites that the core of the present invention is in the form of a tablet.

Present claim 8 and new claim 16 recites that the core is in the form of a capsule.

Barry et al teaches a sustained release preparation comprising nifedipine granules wherein each granule comprises (a) a core of (1) nifedipine and (2) hydroxypropylmethyl cellulose; and (b) a coating covering substantially the whole surface of the core and comprising (1) a water insoluble, water swellable acrylic polymer and (2) a water soluble hydroxylated cellulose derivative.

While the Examiner states that the composition may be in the form of tablets, Barry et al does not disclose a specific embodiment in the form of a tablet or a capsule, **which are coated**.

Rather, Barry et al teaches the coated cores in the form of pellets or granules that are either compressed into a tablet or filled into hard gelatin capsules.

In order to anticipate a claim under 35 U.S.C. § 102, a reference must disclose within the four corners of the document not only all of the elements claimed but also all of the elements arranged or combined in the same way as recited in the claim. *Net MoneyIn, Inc. v. Verisign, Inc.*, 2008 U.S. App. LEXIS 21827, 1, 27 (Fed. Cir. 2008).

More specifically, Barry et al does not disclose "a core in the form of a tablet" or "a core in the form of a capsule" as required by the independent claims. Barry et al specifically discloses coated granules and not a coated tablet or coated capsule. In the cited prior art Barry et al, the core is in the form of pellets or granules. The pellets or granules are coated with the polymers and the coated cores are further either compressed into a tablet or filled into capsules. See page, 4, lines 13-27, which teaches:

> According to the present invention there is provided a sustained-release nifedipine formulation comprising **sufficient granules** to provide a predetermined dose or number of doses of nifedipine, each of said granules having a diameter of between 0.5 and 2.5 mm and comprising: a) a core comprising 100 parts of nifedipine and from 50 to 800 parts of hydroxypropylmethyl cellulose; and b) a coating covering substantially the whole surface of the core and comprising 100 parts of a water insoluble but water swellable acrylic polymer and from to 70 parts of a water soluble hydroxylated cellulose derivative, the weight of the coating being from 2 to 20% of the weight of the core.

For at least this reason, Barry et al does not anticipate the present claims since Barry et al does not teach a specific embodiment which meets all elements of the claimed invention.

Additionally, Barry et al uses low viscosity HPMC which is **not a highly swellable polymer** in the second or outer coating. For this additional reason, Barry et al does not disclose,

teach or suggest all elements of the present claims and, therefore, the present invention is not anticipated.

Accordingly, Applicants respectfully request withdrawal of the rejection based on Barry et al.

B. Egidio et al

Claims 1-12 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Egidio et al United States Patent 5,380,533.

Applicants respectfully traverse the rejection.

In the Abstract, Egidio et al teach:

> Pharmaceutical formulations for oral use coated by an enterosoluble gastro-resistant film containing therapeutically effective amounts of bile acids mixed with physiologically compatible basic substances, which favour bile acids salification and therefore bile acids absorption in the intestinal tract, are the object of the present invention.

Egidio et al further discloses a first coating followed by enterosoluble gastroresistant coating. See column 4, lines 1-20, which states:

> The non-coated pharmaceutical forms obtained according to known methods are transformed into the enterosoluble gastroresistant pharmaceutical formulations object of the present invention by means of a double coating.
>
> The first coating, which is not protective, is carried out by using hydroxypropylmethylcellulose, polyethylene glycol 6000, titanium dioxide, talc and, optionally, pharmaceutically acceptable dyestuffs like, for instance, the iron oxides. This **coating creates a film which acts as support for obtaining** an optimal setting of the subsequent enterosoluble gastroresistant protective film on the pharmaceutical form. Many coating substances can be advantageously used to obtain an enterosoluble gastroresistant coating. Cellulose acetate, the copolymers of the methacrylic acid and of the methacrylic esters in different ratios, commercially known under the trade-mark EUDRAGIT, mainly EUDRAGIT L and EUDRAGIT S, polyvinylacetophthalate and hydroxypropylmethylcellulose phthalate.

The formulation of Edigio et al is very different from the formulation of the present invention as claimed in claims 1, 6, 8 and claim 16.

Particularly, claim 1 and claim 8 are novel in view of Edigio because the present invention comprises: (1) a core in the form of either a tablet or a capsule comprising an agent capable of generating internal pressure on the coat, selected from a group consisting of gas generating agents, highly swellable polymers, superdisintegrants and mixtures thereof; and (2) an expandable coating formed by applying a coating composition comprising a film-forming polymer and one or more expandable components on the tablet core to form a film capable of expanding and maintaining its physical integrity in the gastric milieu, wherein the expandable component is selected from the group consisting of gas generating agents, highly swellable polymers, superdisintegrants and mixtures thereof.

The formulation of Edigio et al is very different from the formulation of the present invention as recited in claim 6 and claim 16 because the present invention comprises: (1) a first coating comprising an agent capable of generating internal pressure on the coat selected from the group consisting of gas generating agents, highly swellable polymers, superdisintegrants and mixtures thereof; and (2) a second coating formed by applying a coating composition comprising a film-forming polymer and one or more expandable components selected from the group consisting of gas generating agents, highly swellable polymers, superdisintegrants and mixtures thereof on the first coating.

In the present invention, the second coating forms a film capable of expanding and maintaining its physical integrity in the gastric milieu Which Edigieo et al does not disclose, teach or suggest.

Although Egidio et al includes a core in the form of a tablet or a capsule Egidio et al does not disclose **an expandable** coating as recited in claim 1 and in claim 8. Thus, Edigio et al does not disclose all elements of the claimed invention. For at least this reason, the present invention is not anticipated by Edigio et al.

The requirement of an expandable component is a characteristic feature of the present invention which distinguishes the claimed invention from the prior art. The expandable components that may be used in the outer coat are selected from the group consisting of gas generating agents, highly swellable polymers, superdisintegrants and mixtures thereof. On the other hand, Egidio et al is silent with respect to any such expandable component.

Moreover, the formulation of Egidio is similar to Comparative examples 1 and 2 of the instant patent application. For example, Comparative example 1 discloses an outer coating that **does not contain any expandable component.** As disclosed in the present specification, when the coated tablet of Comparative example 1 is placed in 100 ml of 0.01N hydrochloric acid, there is no floatation of the coated tablet for up to 8 hours. The tablets also do not swell sufficiently, i.e., are found to swell to only about 1.5 times their volume at the end of 20 hours. Thus, the tablets of Comparative example 1, which are similar to the formulations fo Edigio et al, did not possess desirable characteristics for consistent and prolonged gastric retention.

Another comparative example, Comparative example 2 is described in the original specification at page 26 and Table 2 showing the components of the formulation is reproduced below:

Table 2

Ingredients	Quantity (% w/w)	
Outer coat		
Hydroxypropyl methylcellulose (HPMC E5)	13.04	Coated to a weight gain of about 8.5% by weight of the subcoated core
Eudragit L-100-55	73.91	
Tween 20	0.59	
PEG 400	1.49	
Talc	2.39	

In the tablets of Comparative example 2, the outer coat was devoid of any expandable component, but it contained a coating with a solution of HPMC E5 (low viscosity polymer and NOT highly swellable polymer as claimed) and Eudragit L-100-55. The tablets thus obtained were evaluated to determine the time required to float, i.e., buoyancy time, and the swelling index, i.e., increase in volume of the dosage form. The results are recorded in Table 3 at page 26 of the specification, which is reproduced below.

Table 3

Medium used	**Buoyancy time (minutes)**	**Swelling index at the end of 30 minutes**
0.01N HCl	Did not float till ~7 hours	1.1
pH 4.5 buffer	Did not float till ~7 hours	1.1

As noted in the specification at page 26, the tablets did not float until about 7 hours. Small blisters were seen on the coating at the end of 30 minutes, the coating ruptured within 1 hour and gas was observed to escape in the form of bubbles. Such a coating therefore would not be suitable for a gastric retention system.

In contrast in the working examples of the present specification, Examples 1-12 which included a core comprising agent capable of generating internal pressure on an outer or expandable coating comprising an expandable component and a film forming polymer of the present invention showed very high swelling index, i.e., swelling being achieved rapidly. Thus, the data in the present specification shows that the present invention provides unexpectedly superior results, which could not have been expected based on the disclosure of Edigio et al. Therefore, the present invention is neither anticipated nor obvious over Edigio et al.

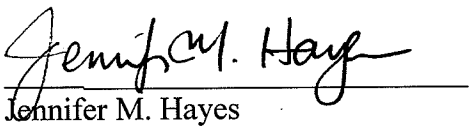
Accordingly, Applicants respectfully request withdrawal of the rejection based on Edigio et al.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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